

PRODUCT ALERT

Clinical Center Standardization Committee



Urine Pregnancy (ICON 25 HCG) Test Kit Lot #HCG030732

Recall

January 2004 (1)

ISSUE

Urine Pregnancy (ICON 25 HCG) Test Kit Lot #HCG030732 has been recalled. DLM used Test Kits from this Lot between December 8th—December 17th, and December 24th—December 30th.

Dr. Glen L. Hortin, Chief of Clinical Chemistry, DLM, explains:

"The kits were recalled because there was the potential for false negative results on urine specimens that have extremely high hCG concentrations (> 100,000 IU/L). The concentrations of hCG may reach these very high values in the circulation of patients with trophoblastic tumors and of some pregnant women at the time of peak hCG production in the eighth to twelfth week of pregnancy. Concentrations of hCG in urine generally are similar or slightly below the serum concentration. The detection of early pregnancy by the urine pregnancy test should not have been affected. Serum pregnancy testing uses a different method and was not involved by this recall. Any testing for hCG as a tumor marker should have used the "beta-hCG tumor marker" serum test which also was not involved. The nature of the problem of a falsely negative pregnancy test in the presence of extremely high hCG levels is pointed out in a recent letter to the New England Journal (Nov 27,2003 349:2172-2173)."

MANAGEMENT

- (1) DLM has removed all kits with Lot #HCG030732.
- (2) MMD has none of the recalled Lot# and did not distribute the recalled Lot #.
- (3) Approved POCT for urine pregnancy can continue to use Urine Pregnancy Kits (Item #02746) received from MMD.
- (4) Users should double check their lot numbers. Users should be recording which lot they have been using for quality control purposes so they will have records of whether or not they ever had that lot number. If, by some circumstance, Users identify Lot #HCG030732, they should return these kits to CHS and order replacement from the Visual Supply Catalog (Item #02746). They should then contact Dr. Hortin in DLM and notify the PI on their protocols to determine the next steps.
- (5) Staff with any questions regarding this Urine Pregnancy Test Kit recall, the results in a specific patient, or other issues related to hCG testing, please feel free to contact the DLM Chemistry Section Urine Group or Dr. Hortin at 301-496-3386.